



Misguided Mandate: Why Pre-Adolescent and Adolescent Girls Should be Able to Choose Whether to Receive the Human Papillomavirus

Citation

Hillary W. Steinbrook, Why Pre-Adolescent and Adolescent Girls Should be Able to Choose Whether to Receive the Human Papillomavirus [2010]

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INTRODUCTION

Much has been written about Gardasil©, the Human Papillomavirus (HPV) vaccine manufactured by Merck (Merck & Co., Inc., Whitehouse Station, N.J.) and approved by the Food and Drug Administration (FDA) in 2006¹. Intended to protect recipients from developing genital condylomata (warts) and, more significantly, precancerous genital lesions that eventually could lead to cancer of the cervix, vagina, and vulva², Gardasil© understandably has received substantial attention due to its medical merits. However, the manner in which Merck introduced Gardasil© to the public caused the vaccine to be surrounded by controversy almost immediately³. Instead of waiting to conduct further safety and efficacy testing, establishing a viable system for interested individuals to receive the vaccine at an affordable price, or engaging in a widespread educational campaign to teach consumers why the HPV vaccine is necessary, Merck pushed ahead with strong lobbying efforts in an attempt to achieve the implementation of state legislation making HPV vaccination mandatory. Merck's political maneuvering led to an uproar in some states and eventually motivated the manufacturer to change its strategy and halt its lobbying efforts⁴.

¹ Margaret J. Kochuba, *Public Health vs. Patient Rights: Reconciling Informed Consent with HPV Vaccination*, 58 EMORY L.J. 761, 761-62 (2009).

² FDA News Release, *FDA Approves Expanded Uses for Gardasil to Include Preventing Certain Vulvar and Vaginal Cancers*, (Sept. 12, 2008), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116945.htm>

³ See Stephanie Saul & Andrew Pollack, *Furor on Rush to Require Cervical Cancer Vaccine*, N.Y. TIMES, Feb. 17, 2007, at 1; *Profit and Public Health: A Useful Vaccine, and a Tone-Deaf Lobbying Campaign on its Behalf*, THE WASHINGTON POST, Feb. 11, 2007, at B06.

⁴ See Amy Gardner, *Merck to Stop Pushing to Require Shots*, THE WASHINGTON POST, Feb. 21, 2007, at B10; Lianne Hart, *Uproar Over HPV Vaccine Order*, LOS ANGELES TIMES, Feb. 25, 2007, at 25.

The literature on the HPV vaccine discusses in detail the elements of the controversy already outlined above: the lack of extensive testing, high price of the vaccine, and lack of knowledge among consumers regarding the connection between HPV and cervical cancer. A particularly salient aspect of the Gardasil© debate, the current mandatory status of HPV vaccination in some states and pending legislation to the same effect in other states dominates the conversation⁵. Literature focusing on reactions to the vaccination mandate often considers three issues that have become interrelated in this context: rejection of vaccinations, unease regarding government mandates, and opposition to interference by drug companies and state governments in the sexual activity of pre-adolescent and adolescent girls⁶. At times, these issues can be conflated and it is difficult to determine exactly what aspect of the HPV vaccination mandate has aroused an individual's anger.

However, one element of the conversation about the mandate that seems to remain constant is the focus on the removal of parental choice. Authors discuss the encroachment of governmental activity on parents' rights to raise their children as they see fit and the difficulty faced by parents in opting-out of the HPV vaccination mandate⁷. In contrast, much less attention has been paid to the attitudes, values, rights, and abilities of the girls and young women who have been targeted as Gardasil© recipients. Making HPV vaccination mandatory was hasty, given the lack of testing, high price of the vaccine, and lack of knowledge among consumers

⁵ Gillian Haber, Robert M. Malow, & Gregory D. Zimet, *The HPV Vaccine Mandate Controversy*, 20 JOURNAL OF PEDIATRIC AND ADOLESCENT GYNECOLOGY 325 (2007).

⁶ Ellen Goodman, *A Dose of Reality on HPV Vaccine*, THE BOSTON GLOBE, March 2, 2007, at A19.

⁷ See Judy Peres & Bruce Japsen, *States Craft HPV Vaccine Bills*, CHICAGO TRIBUNE, Feb. 11, 2007, at 3; Liz Austin Peterson, *Texas Governor Orders HPV Vaccinations for Schoolgirls*, CHICAGO TRIBUNE, Feb. 3, 2007, at 4; *Merck Funds Effort to Pass Vaccine Laws*, LOS ANGELES TIMES, Jan. 31, 2007, at 3; Saul & Pollack, *supra* note 3; Haber et al., *supra* note 5, at 326; Marilyn Larkin, *HPV Vaccine Mandate Stirs Controversy in USA*, 7 THE LANCET 251 (2007).

who could not understand why it was necessary to receive the vaccine. This move also was inappropriate. It denied individuals who are competent to make their own medical decisions the opportunity to decide whether such a vaccination was medically indicated given their choices regarding sexual activity and reasonable based on the level of risk they were comfortable assuming. When psychological research on the ability of pre-adolescents and adolescents to make medical choices affecting their own bodies is analyzed alongside statutory law governing the age of consent in the 50 states, it becomes clear that a vaccine designed specifically to combat a disease that results from personal, sexual contact should not have been made the subject of a legislative mandate of which only parents could opt out.

CAUSES, COSTS, AND CONSEQUENCES OF HPV

The disease that Gardasil© is intended to prevent occurs in stages. Most women who contract HPV will never develop cervical cancer. In many instances, the infection never causes symptoms, and the immune system clears the infection before it becomes cancerous. In other instances, women contract types of HPV that do not lead to cancer, or they contract types of HPV that can lead to cancer but do not actually develop cancer⁸. The types of HPV that can lead to cervical cancer account for slightly more than 3% of infections⁹. HPV is a broad category that includes more than 100 viruses, of which approximately 30 are sexually transmitted¹⁰. Of these 30 types, approximately 90% of genital warts cases are caused by types 6 and 11, and

⁸ FDA News Release, *FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus: Rapid Approval Marks Major Advancement in Public Health*, (June 8, 2006), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108666.htm>

⁹ Lawrence O. Gostin & Catherine D. DeAngelis, *Mandatory HPV Vaccination: Public Health vs. Private Wealth*, 297 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1921, 1921 (2007).

¹⁰ *Gardasil (Human Papillomavirus Vaccine) Questions and Answers*, Vaccines, Blood & Biologics, (June 8, 2006), <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm096052.htm>

approximately 70% of cervical cancer cases are caused by types 16 and 18¹¹. HPV also can cause cancer of the vulva, vagina, anus, penis, head, or neck¹²; it is HPV's causal connection to these latter four forms of cancer that has contributed in part to efforts to test Gardasil© for efficacy in, and promote the vaccination of, boys and men.

Since effective screening methods for cervical cancer, such as Papanicolaou (Pap) tests, already exist in the United States, the physical, emotional, and monetary costs of HPV and cervical cancer are more significant in other countries where such screening methods are not as readily available¹³. Women in the United States who die from cervical cancer usually did not get Pap tests¹⁴. Nevertheless, in the United States, HPV still is the most common Sexually Transmitted Infection (STI)^{15,16}. Contracting the infection is strongly associated with the female's number of sexual partners; preventing and treating conditions caused by HPV cost approximately \$4 billion (2004 dollars) in the United States annually¹⁷. Approximately 6 million new cases of HPV are reported annually in the United States¹⁸. More than half of sexually active men and women will contract HPV at some point¹⁹; currently, approximately 20 million people

¹¹ Karen Springen, *Why Are HPV Vaccine Rates so Low?*, NEWSWEEK, (Feb. 25, 2008), <http://www.newsweek.com/id/115329>.

¹² Department of Health and Human Services, Centers for Disease Control and Prevention, *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunizations Practices*, 56 MORBIDITY AND MORTALITY WEEKLY REPORT at 2, (March 23, 2007), <http://www.cdc.gov/mmwr/pdf/rr/rr5602.pdf>. [hereinafter ACIP MMWR]

¹³ Elisabeth Rosenthal, *Drug Makers' Push Leads to Cancer Vaccines' Rise*, N.Y. TIMES, Aug. 20, 2008, at 1.

¹⁴ *Id.*

¹⁵ In this paper, I will use the terms Sexually Transmitted Infection (STI), Sexually Transmitted Disease (STD), and Venereal Disease (VD) interchangeably.

¹⁶ Charlotte Haug, *The Risks and Benefits of HPV Vaccination*, 302 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 795, 795 (2009).

¹⁷ ACIP MMWR, *supra* note 12, at 15.

¹⁸ James Colgrove, *The Ethics and Politics of Compulsory HPV Vaccinations*, 355 THE NEW ENGLAND JOURNAL OF MEDICINE 2389, 2389 (2006).

¹⁹ Lisa E. Manhart, King K. Holmes, Laura A. Koutsky, Troy R. Wood, Donna L. Kenney, Qinghua Feng, & Nancy B. Kiviat, *Human Papillomavirus Infection Among Sexually Active Young Women in the United States: Implications*

in the United States have HPV²⁰. Among those women who have contracted forms of HPV that can lead to cervical cancer, approximately 12,000 develop cancer annually and approximately 4,000 die from cervical cancer annually²¹. In the United States, cervical cancer is the eleventh most common form of cancer²². In contrast, approximately 400,000 new cases of cervical cancer occur annually worldwide, and more than 200,000 women die from cervical cancer annually worldwide, where cervical cancer is the second most common cancer in women²³.

Unlike other diseases for which vaccines have been developed, such as smallpox and polio, both of which will be discussed below, HPV is transmitted nearly always through personal, sexual contact. HPV cannot be transmitted through typical casual, classroom interaction even when peers are in close quarters²⁴. Therefore, the need to vaccinate pre-adolescent and adolescent girls depends on the manner in which they can contract the infection, the time at which they are most likely to contract the infection, and the probability that they will do so. In 2007, just under half of all high school students reported having had sexual intercourse. The median age of sexual debut is 16.9 years for males and 17.4 years for females²⁵. In 2000, approximately 9.1 million individuals between the ages of 15 and 24 developed new STIs; of

for *Developing a Vaccination Strategy*, 33 SEXUALLY TRANSMITTED DISEASES 502, 502 (2006). [hereinafter Manhart et al.]

²⁰ Melissa Jones & Robert Cook, *Intent to Receive an HPV Vaccine Among University Men and Women and Implications for Vaccine Administration*, 57 JOURNAL OF AMERICAN COLLEGE HEALTH 23, 23 (2008).

²¹ *Gardasil Vaccine Safety: Information from FDA and CDC on the Safety of Gardasil Vaccine*, Vaccines, Blood & Biologics, (Aug. 20, 2009),

<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm179549.htm>

²² Robert Steinbrook, *The Potential of Human Papillomavirus Vaccine*, 354 The New England Journal of Medicine 1109, 1109 (2006).

²³ Centers for Disease Control and Prevention, *Vaccine Safety: Information from FDA and CDC on Gardasil and its Safety (Archived)*, (July 22, 2008), <http://www.cdc.gov/vaccinesafety/Vaccines/HPV/HPVArchived.html>

²⁴ Haber et al., *supra* note 5, at 326.

²⁵ Kaiser Family Foundation, *Sexual Health of Adolescents and Young Adults in the United States*, (Sept. 2008), http://www.kff.org/womenshealth/upload/3040_04.pdf. [hereinafter Kaiser 2008]

these cases, 51% were caused by HPV²⁶. Two elements can be drawn from these statistics that are particularly important in the debate over making HPV vaccination subject to a mandate of which only parents can opt out: barely half of high school students have sexual intercourse, and the median age of sexual debut for females is in late adolescence. Moreover, the vast majority of adolescents between the ages of 15 and 17 who have never had sex identify concerns about contracting STDs and feeling too young as motivations for waiting²⁷.

HUMAN PAPILLOMAVIRUS QUADRIVALENT (TYPES 6, 11, 16, 18) VACCINE, RECOMBINANT: GARDASIL©

In June 2006, the FDA approved Gardasil© for use in females between the ages 9 and 26 to prevent precancerous lesions, cervical cancer, and genital warts²⁸. Subsequently, the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommended that all girls between the ages of 11 and 12 receive the three-dose vaccination series. ACIP chose this age range so that girls could receive the vaccine before they become sexually active and exposed to HPV as a result. ACIP based its recommendation on its evaluation of data regarding the safety, immunogenicity, efficacy, acceptability, and cost effectiveness of the vaccine, as well as data regarding the epidemiology of the underlying disease and behavior that could affect the spread of the disease²⁹. In September 2008, the indications for Gardasil© were expanded to include the prevention of vaginal and vulvar cancers, which also can be caused by HPV³⁰. In October 2009, the FDA approved the vaccine for use in males

²⁶ Kaiser 2008, *supra* note 25.

²⁷ Kaiser Family Foundation, *U.S. Teen Sexual Activity*, (Jan. 2005), <http://www.kff.org/youthhivstds/upload/U-S-Teen-Sexual-Activity-Fact-Sheet.pdf>. [hereinafter Kaiser 2005]

²⁸ *Gardasil Vaccine Safety: Information from FDA and CDC on the Safety of Gardasil Vaccine*, *supra* note 21.

²⁹ ACIP MMWR, *supra* note 12, at 2.

³⁰ FDA News Release, *supra* note 2.

between the ages of 9 and 26 to prevent genital warts³¹. Gardasil© is the first vaccine approved to prevent these conditions³². In both the June 2006 Approval Letter and October 2009 Approval Letter from the FDA's Center for Biologics Evaluation and Research (CBER), the director of the Office of Vaccines Research and Review acknowledges Merck's commitment to conduct a variety of post-marketing follow up studies on vaccine recipients of both genders to evaluate safety and effectiveness. Merck committed to look specifically at pregnancy outcomes, a controversial area after the thalidomide tragedy, as well as possible replacement, as a result of widespread vaccination, of conditions caused by the four types of HPV against which Gardasil© protects with conditions caused by types of HPV against which Gardasil© does not provide any protection³³. It is particularly important for Merck to investigate the long-term effects of Gardasil©, given the short time frame during which it conducted its initial safety and efficacy studies.

Merck's vaccine is a recombinant vaccine; since it only contains virus protein, rather than the entire virus, Gardasil© cannot cause infection³⁴. The FDA touts the impressive efficacy of the vaccine: it is nearly 100% effective in females in preventing both the precancerous lesions caused by HPV types 16 and 18, and the genital warts caused by HPV types 6 and 11³⁵. In men,

³¹ FDA News Release, *FDA Approves New Indication for Gardasil to Prevent Genital Warts in Men and Boys*, (Oct. 16, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm187003.htm>

³² Lindsey R. Baden, Gregory D. Curfman, Stephen Morrissey, & Jeffrey M. Drazen, *Human Papillomavirus – Opportunity and Challenge*, 356 THE NEW ENGLAND JOURNAL OF MEDICINE 1990, 1990. (2007). [hereinafter Baden et al.]

³³ See Department of Health and Human Services, *Approval Letter – Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant*, Vaccines, Blood & Biologics, (June 8, 2006), <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm111283.htm>; Department of Health and Human Services, *Approval Letter – Gardasil*, Vaccines, Blood & Biologics, (Oct. 16, 2009), <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm186991.htm>

³⁴ *Gardasil (Human Papillomavirus Vaccine) Questions and Answers*, *supra* note 10.

³⁵ FDA News Release, *supra* note 8.

the vaccine is 90% effective in preventing genital warts³⁶. Nevertheless, Gardasil© can protect against only these four types of HPV³⁷. Thus, regular Pap screenings still are necessary for women³⁸. Additionally, to achieve optimum effectiveness, the three-dose vaccination series must be received before the patient has been exposed to the types of HPV against which Gardasil© protects³⁹. However, ACIP does recommend catch up vaccines for females between the ages of 13 and 26 who have not begun or completed the series⁴⁰, and no adverse effects have been reported as a result of receiving the vaccine late⁴¹. More than one quarter of girls in the United States between the ages of 13 and 17 has received at least one dose⁴².

Physicians and potential consumers have challenged the wisdom of FDA's rapid approval of Gardasil© after six months through their priority review process⁴³, raising questions about various aspects of the six studies conducted on females before Gardasil© was approved⁴⁴. Four randomized, double-blind, placebo-controlled studies investigated the safety and efficacy of the vaccine in 21,000 females between the ages of 16 and 26⁴⁵; these studies established the nearly 100% effectiveness of the vaccine. However, the recipients of the vaccine were followed for only five years after vaccination⁴⁶, and cervical, vaginal, and vulvar cancers can be expected to

³⁶ FDA News Release, *supra* note 31.

³⁷ FDA News Release, *supra* note 2.

³⁸ *Gardasil (Human Papillomavirus Vaccine) Questions and Answers*, *supra* note 10.

³⁹ Baden et al., *supra* note 32, at 1990.

⁴⁰ ACIP MMWR, *supra* note 12, at 16.

⁴¹ Jones & Cook, *supra* note 20, at 24.

⁴² Sheila M. Rothman & David J. Rothman, *Marketing HPV Vaccine: Implications for Adolescent Health and Medical Professionalism*, 302 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 781, 781 (2009).

⁴³ FDA News Release, *supra* note 8.

⁴⁴ Kochuba, *supra* note 1, at 771.

⁴⁵ See ACIP MMWR, *supra* note 12, at 8-12; Gail Javitt, Deena Berkowitz, & Lawrence O. Gostin, *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J.L. MED. & ETHICS 384, 385 (2008). [hereinafter Javitt et al.]

⁴⁶ ACIP MMWR, *supra* note 12, at 11.

develop many years – possibly as long as 20 to 40 years⁴⁷ – after exposure to the disease. The effectiveness studies were based on the premise that absence of lesions within five years implies prevention of cancer⁴⁸, a conclusion with which some individuals are not satisfied⁴⁹. It is important to note that consciously allowing any of the study participants to develop cancer would not have been permitted; ACIP explains that “the standard of care is to screen and treat [precancerous] lesions to prevent invasive cervical cancer”⁵⁰. Additionally, studies of Gardasil© indicated that its effectiveness may decrease after three to five years⁵¹. The short time period during which the effects of the vaccine were monitored and confirmed has contributed to the debate regarding the appropriate age at which receipt of the vaccine should be mandated. When the effectiveness of a vaccine intended to protect against an STI has been demonstrated over a period of only five years, administering the vaccine to girls as young as 11 and 12 years old may be inappropriate⁵².

Additionally, two studies evaluated the immunogenicity response in pre-adolescent and adolescent females between the ages of 9 and 15. Since the immune responses were similar in both age groups studied, the investigators concluded that effectiveness levels also should be similar between the two groups⁵³. However, some commentators worry that the lack of effectiveness testing in this younger age group represents a gap in the data that should have been

⁴⁷ Haug, *supra* note 16, at 795.

⁴⁸ See FDA News Release, *supra* note 8; Javitt et al., *supra* note 45, at 385 (2008).

⁴⁹ Baden et al., *supra* note 32, at 1990.

⁵⁰ ACIP MMWR, *supra* note 12, at 8.

⁵¹ See Rosenthal, *supra* note 13; David Brown, *Millions in U.S. Infected with HPV*, THE WASHINGTON POST, Feb. 28, 2007, at A01.

⁵² Rosenthal, *supra* note 13.

⁵³ FDA News Release, *supra* note 8.

corrected before mandates that apply to members of this cohort were considered and imposed⁵⁴.

Likewise, the effectiveness of the vaccine was studied in 4,055 males between the ages of 16 and 26, and the immune response was studied in pre-adolescent and adolescent males between the ages of 9 and 15. Since the immune responses were similar in both age groups, the investigators concluded that effectiveness levels also should be similar between the two groups⁵⁵.

According to the assurances directed to the public by the FDA and CDC, Gardasil© is safe, effective, and the subject of continuing analysis through the Vaccine Adverse Event Reporting System (VAERS). Vaccine recipients or their family members, healthcare workers, and the vaccine manufacturer can submit to VAERS reports of adverse events that take place after vaccination occurs. VAERS staff evaluates these reports to determine whether any patterns appear in the adverse events that suggest a link between receipt of vaccination and the type of adverse event⁵⁶. According to a study by the FDA and CDC, the distribution of adverse events related to HPV vaccination that were reported to VAERS between June 2006 and December 2008 were comparable to reports received relating to meningitis and Tdap (tetanus, diphtheria, pertussis) vaccines; these vaccines also are recommended for individuals between the ages of 9 and 26⁵⁷. By September 2009, when more than 26 million doses of Gardasil© had been administered in the United States, approximately 15,000 adverse events had been reported to VAERS. Among the adverse event reports, 93% were non-serious and include syncope

⁵⁴ Joseph De Soto, *Should HPV Vaccination be Mandatory?*, 56 THE JOURNAL OF FAMILY PRACTICE 267, 267 (2007).

⁵⁵ FDA News Release, *supra* note 31.

⁵⁶Centers for Disease Control and Prevention, *Vaccine Safety: Summary of HPV Adverse Event Reports Published in JAMA*, (Jan. 15, 2010), <http://www.cdc.gov/vaccinesafety/Vaccines/HPV/jama.html>

⁵⁷ Barbara A. Slade, Laura Leidel, Claudia Vellozzi, Emily Jane Woo, Wei Hua, Andrea Sutherland, Hector S. Izurieta, Robert Ball, Nancy Miller, M. Miles Braun, Lauri E. Markowitz, & John Iskander, *Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine*, 302 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 750 (2009), cited in Centers for Disease Control and Prevention, *supra* note 56.

(fainting), pain and redness at injection site, dizziness, nausea, fever, and headache. The remaining 7% were serious; these events include life threatening illness, death, permanent disability, or hospitalization. The CDC states that no pattern has been established among the deaths that followed receipt of the HPV vaccination⁵⁸. Additionally, the CDC explains that no link can be drawn between vaccination and Guillain-Barré Syndrome (GBS), a neurological disorder that can be caused by a variety of infections⁵⁹, although the National Vaccine Information Center is not as sanguine about a lack of connection between Gardasil© and GBS⁶⁰. As the CDC emphasizes, causation cannot be established simply as the result of a temporal relationship⁶¹.

However, syncope and blood clots have been reported in disproportionately high numbers after receipt of the HPV vaccine, leading the FDA and CDC to investigate these specific conditions further. Many of the individuals who suffered blood clots already were at a higher risk for developing clots because they were taking oral contraceptives⁶². This potential interaction between birth control pills and Gardasil© is particularly frightening because sexually active individuals are most likely to both take oral contraceptives and receive the HPV vaccine. Furthermore, if efforts to switch oral contraceptives from by prescription only status to over the counter status are successful⁶³, then healthcare workers will need to ask each patient whether she is on birth control before administering the vaccine. According to the CDC, syncope commonly

⁵⁸ Centers for Disease Control and Prevention, *Vaccine Safety: Questions and Answers about HPV Vaccine Safety*, (Jan. 15, 2010), http://www.cdc.gov/vaccinesafety/Vaccines/HPV/hpv_faqs.html

⁵⁹ Centers for Disease Control and Prevention, *Vaccine Safety: Reports of Health Concerns Following HPV Vaccination*, (Jan. 15, 2010), <http://www.cdc.gov/vaccinesafety/Vaccines/HPV/gardasil.html>

⁶⁰ Kochuba, *supra* note 1, at 762.

⁶¹ Centers for Disease Control and Prevention, *supra* note 59.

⁶² Centers for Disease Control and Prevention, *supra* note 56.

⁶³ Mayelin Prieto-Gonzalez, *Empowering Women: A Feminist Argument for Over-the-Counter Sale of Oral Contraceptives* (2005), in Peter Barton Hutt, ed., *Food and Drug Law: An Electronic Book of Student Papers*.

occurs in pre-adolescents and adolescents immediately after receiving a vaccine. However, the frequency of reports of syncope was severe enough to motivate the FDA to ask Merck to revise the Gardasil© label to remind healthcare workers to watch carefully any vaccine recipient for 15 minutes after vaccination and recommend that the recipient sit or lie down for this time to avoid head injuries from falls⁶⁴. None of the reported adverse events has led the CDC to change its recommendations or the FDA to change its prescribing information⁶⁵.

STATE RESPONSES

Within four months after the FDA approved Gardasil© for use in females between the ages of 9 and 26, and ACIP recommended administration of the vaccine to girls between the ages of 11 and 12, the Michigan Senate already had introduced legislation that would have required girls to receive the vaccination before they would be permitted to enter sixth grade⁶⁶. In 2006 and 2007, 41 states and the District of Columbia introduced and considered legislation relating to HPV⁶⁷. Two more states entered the debate during the 2007-2008 legislative session⁶⁸, and another state introduced legislation in the 2009-2010 legislative session⁶⁹. Three common elements can be found in the bills regarding HPV: the provision of educational materials about the link between HPV and cervical cancer and the availability of the new vaccine, insurance coverage or other methods of funding vaccine administration, and whether the receipt of the

⁶⁴ Centers for Disease Control and Prevention, *supra* note 56.

⁶⁵ *Gardasil Vaccine Safety: Information from FDA and CDC on the Safety of Gardasil Vaccine*, *supra* note 21.

⁶⁶ Michigan S.B. 1416; National Conference of State Legislatures, *HPV Vaccine*, (Feb. 2010), <http://www.ncsl.org/IssuesResearch/Health/HPVVaccineStateLegislation/tabid/14381/Default.aspx>

⁶⁷ These states are Arizona, Arkansas, California, Colorado, Connecticut, D.C., Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and West Virginia. National Conference of State Legislatures, *supra* note 66.

⁶⁸ These states are Louisiana and Wisconsin. National Conference of State Legislatures, *supra* note 66.

⁶⁹ This state is Alabama. National Conference of State Legislatures, *supra* note 66.

HPV vaccine should be made mandatory for girls entering sixth grade when they are most likely to be 11 or 12 years old. Although only Virginia and the District of Columbia have enacted legislation that currently imposes a vaccination requirement⁷⁰, more than 20 other states also considered legislation that would have imposed a mandate⁷¹. Most of these states included in the legislation that would have imposed an HPV vaccination mandate an opt-out provision to provide parents with the option of refusing that their daughters be vaccinated. Arizona⁷² and Texas⁷³ took the opposite stance, introducing legislation that would prohibit an HPV vaccination mandate. In Texas, legislators acted quickly to override an executive order by the governor in February 2007 that mandated HPV vaccination for girls entering the sixth grade⁷⁴, the first such requirement imposed in the United States⁷⁵. More recently, Texas has reconsidered this shift and introduced legislation that would allow the imposition of an HPV vaccination mandate⁷⁶. Conversely, the Virginia legislature is considering whether to remove the vaccination requirement⁷⁷. Kansas appears to be unique in introducing a resolution directed specifically to the FDA, in which the state would urge the FDA to “use caution in approving new vaccines such as Gardasil© which has had a number of health problems”⁷⁸.

⁷⁰ Virginia: Va. Chapter No. 922 (2007) and Va. Chapter No. 858 (2007); D.C.: B.17-0030.

⁷¹ These states are California (A.B. 16), Colorado (S.B. 80), Connecticut (H.B. 6977), Florida (S.B. 660), Georgia (S.B. 155), Illinois (H.B. 115, S.B. 10), Kansas (H.B. 2227), Kentucky (H.B. 143, H.B. 345, H.B. 396, H.B. 69), Maryland (S.B. 54), Massachusetts (Doc 604, S.B. 102), Michigan (H.B. 4164, H.B. 4104, H.B. 5171, S.B. 133), Missouri (H.B. 802, S.B. 514), Minnesota (S.F. 243), Mississippi (H.B. 895), New Mexico (S.B. 1174, S.B. 244), New York (S.B. 4394, A.B. 5810, A. 778), Ohio (H.B. 81), Oklahoma (S.B. 487), South Carolina (H.B. 3136), Vermont (S.B. 256, S.B. 139), and West Virginia (H.B. 2835). National Conference of State Legislatures, *supra* note 66.

⁷² Arizona S.B. 1093

⁷³ Texas H.B. 1098

⁷⁴ Texas Executive Order 4 (Feb. 2, 2007)

⁷⁵ National Conference of State Legislatures, *supra* note 66.

⁷⁶ Texas H.B. 2220

⁷⁷ Virginia H.B. 686

⁷⁸ Kansas H.R. 6019

In addition to explicit opt-out provisions provided in some of the HPV vaccination-specific legislation, all 50 states provide some form of opt-out option regarding vaccination in general. Every state offers a medical exemption, allowing a child to avoid vaccination if a physician states that the vaccination would harm the child as a result of the child's physical condition⁷⁹. Another form of exemption from vaccination, either for religious reasons, philosophical reasons, or both, is available in 48 states⁸⁰. Only Mississippi and West Virginia do not permit either a religious or philosophical exemption to vaccination; both states have declared religious exemptions unconstitutional⁸¹. States are not required to provide religious exemptions⁸². When religious and philosophical exemptions are available, they may be enforced inconsistently or require complicated paperwork⁸³. Some courts have refused to uphold religious and philosophical exemptions when they did not believe that the particular claims for exemption were valid⁸⁴. When a claim for exemption goes unchallenged or is upheld, it may require that the individual who is the subject of the exemption not receive any vaccinations⁸⁵. As a result of inconsistent or overly broad enforcement, some individuals may be deterred from claiming an exemption. Consequently, their children will be required to receive a vaccination of which their parents do not approve. Alternatively, physicians worry that the addition of a controversial

⁷⁹ Giuseppe Aguanno, *Cervical Cancer Prevention: Mandating the HPV Vaccine as a Condition of School Attendance*, 46 FAM. CT. REV. 637, 645 (2008).

⁸⁰ *Id.*

⁸¹ *Id.* at 647.

⁸² Julie E. Gendel, *Playing Games with Girls' Health: Why it is Too Soon to Mandate the HPV Vaccine for Pre-Teen Girls as a Prerequisite to School Entry*, 39 SETON HALL L. REV. 265, 282-83 (2009), citing Employment Division v. Smith, 494 U.S. 872 (1990), and Douglas County v. Anaya, 694 N.W.2d 601 (Neb. 2005).

⁸³ Jonathan T. Scott, *The Difficult Road to Compelling Vaccination for Sexually Transmitted Diseases – How Gardasil and Those to Follow Will Change the Way That States Require Inoculation*, 97 KY. L.J. 697, 710-11 (2008-2009).

⁸⁴ *Id.*

⁸⁵ Kochuba, *supra* note 1, at 783.

vaccine to the mandatory vaccination regimen may lead parents who are sufficiently motivated to avoid this specific vaccine to opt out of having their children receive other vaccinations⁸⁶; in states with general – as opposed to partial – exemptions, such a situation is the necessary result of claiming an exemption to any vaccine. This choice, if made by a sufficient number of individuals, could contribute to an increase in incidence of other diseases that can be prevented through vaccination⁸⁷. Additionally, the creation of an HPV vaccine mandate with broad, permissive exemption provisions could set a precedent for legislators to act similarly in the future, thereby also contributing to the increase in incidence of preventable diseases⁸⁸.

The vast majority of states permit only a parent or guardian to elect to opt-out of vaccinating his or her child⁸⁹. The exemption for religious beliefs variably refers to the religious beliefs of the child who would be receiving the vaccination or to the beliefs of the child's parents, but it appears that the parent must decide whether to claim the exemption. Several states permit an emancipated minor to opt-out of vaccination⁹⁰. Louisiana appears to be unique in permitting a child to claim an exemption from mandatory vaccination⁹¹. Similarly, Virginia's general vaccination exemption statute seems to allow a child to claim an exemption; however, the statute includes a provision explicitly stating that only a parent or guardian may opt-out of the administration of the HPV vaccine⁹². Oregon's vaccination exemption statute is unique in

⁸⁶ Susan Levine, *Parents Question HPV Vaccine: Push to Mandate Shots Rapidly Creates Backlash*, THE WASHINGTON POST, March 4, 2007, at C01.

⁸⁷ Scott, *supra* note 83, at 697-98.

⁸⁸ Gostin & DeAngelis, *supra* note 9, at 1922.

⁸⁹ National Conference of State Legislatures, *States with Religious and Philosophical Exemptions from School Immunization Requirements*, (Dec. 2009), <http://www.ncsl.org/Default.aspx?TabId=14376>

⁹⁰ See e.g. California: Cal. Health & Safety Code § 120325 et seq.; Colorado: Colo. Rev. Stat. § 25-4-902, 903; Minnesota: Minn. Stat. Ann. § 121A-15; and Pennsylvania: 28 Pa. Code § 23-83, 84.

⁹¹ La. Rev. Stat. Ann. § 17:170(A); 40:31.16

⁹² Va. Code Ann. § 22.1-271.2, § 32.1-46

referring to the accepted age of consent to medical care; thus, in Oregon, a parent or guardian, an emancipated minor, or an individual over the age of 15 may claim an exemption from vaccination⁹³. Therefore, at least in Oregon, there is recognition of the fact that individuals below the age of majority are competent to make decisions regarding which vaccinations they receive. However, Oregon still is enforcing an opt-out regime, which is an inappropriate system to apply to HPV vaccination.

Controversy regarding HPV vaccination mandates arose due both to the content of the bills and the manner in which they were formulated. Before Merck received FDA approval for Gardasil®, the drug manufacturer began to put in place a lobbying campaign to urge state legislators to propose bills that would mandate vaccination⁹⁴. Merck provided funding directly to legislators, including members of the bipartisan advocacy group Women in Government who subsequently introduced and advocated for some of the bills at issue that would impose a vaccine mandate⁹⁵. The relationship between Merck and the government was viewed with particular suspicion in Texas, where Governor Rick Perry's former chief of staff worked as a lobbyist for Merck, and Perry received several thousand dollars from Merck's political action committee⁹⁶. This connection contributed to the Texas legislature's outrage over the governor's executive order mandating vaccination⁹⁷. On a larger scale, individuals who are wary of drug companies' motives pointed to the enormous profit that Merck stood to make if Gardasil® became a required vaccination. Merck's concurrent competition with GlaxoSmithKline, another drug manufacturer that was in the process of developing Cervarix®, also signaled that perhaps Merck was acting

⁹³ Or. Rev. Stat. § 433.267

⁹⁴ Saul & Pollack, *supra* note 3.

⁹⁵ See *Merck Funds Effort to Pass Vaccine Laws*, *supra* note 7; Colgrove, *supra* note 18, at 2390.

⁹⁶ Peterson, *supra* note 7.

⁹⁷ Hart, *supra* note 4.

out of a desire to win a race to dominate the market rather than protect public health⁹⁸.

Cervarix®, which was approved by the FDA in October 2009, is a vaccine that also protects against cervical cancer caused by HPV types 16 and 18⁹⁹. The backlash caused by factors related to Merck's methods, rather than Gardasil's medical merits, dominated media reports covering discussions of the pending legislation¹⁰⁰. Realizing that its lobbying activities had become self-defeating, Merck ended these efforts in February 2007¹⁰¹.

Individuals also objected to the speed with which legislation mandating vaccination was being considered. Other vaccines intended to protect against common and more easily transmitted childhood diseases, such as varicella (chicken pox), became mandated after several years of testing and observation¹⁰². Even ACIP, which made the original recommendation that girls between the ages of 11 and 12 receive the vaccination, objected to making vaccination mandatory once the issue was raised by state legislatures¹⁰³. ACIP had not considered making the vaccination mandatory¹⁰⁴. The chair of ACIP at the time that the committee had recommended vaccination emphasized that prohibiting children from attending school if they have not been vaccinated against HPV is inappropriate¹⁰⁵. The American Cancer Society and the American Academy of Pediatrics also recommend vaccination but do not support a mandate¹⁰⁶.

⁹⁸ Saul & Pollack, *supra* note 3.

⁹⁹ Carol Cruzan Morton, *The Dollars and Sense of Vaccination for Cervical Cancer*, FOCUS: NEWS FROM HARVARD MEDICAL, DENTAL, AND PUBLIC HEALTH SCHOOLS, (Jan. 8, 2010), http://focus.hms.harvard.edu/2010/010810/cervical_cancer.shtml

¹⁰⁰ Email correspondence with Robert Steinbrook, former Deputy Editor of and National Correspondent for The New England Journal of Medicine (Jan 19, 2010).

¹⁰¹ Gardner, *supra* note 4.

¹⁰² See Levine, *supra* note 86; Saul & Pollack, *supra* note 3.

¹⁰³ Elisha Baron, *Federal Law Requires HPV Vaccine for Green Card Applicants: Valid Exercise of State Police Powers?*, 37 J.L. MED. & ETHICS 149, 150 (2009).

¹⁰⁴ Levine, *supra* note 86.

¹⁰⁵ *Id.*

¹⁰⁶ Gardner, *supra* note 4.

Providing education seemed to be a more reasonable first step, not only to inform potential consumers about the benefits of being vaccinated but also to inform females who lack knowledge regarding the underlying disease¹⁰⁷. Less than half of women have heard of HPV, and less than half of these women are aware of a connection between HPV and cervical cancer¹⁰⁸. Quickly mandating a vaccine that is intended to prevent a mysterious disease would increase distrust for drug companies and state governments¹⁰⁹. Recognizing this dilemma, many state legislatures have considered bills that instead focus on educational campaigns¹¹⁰. Ideally, the information conveyed through these campaigns will focus strongly on medicine and science, rather than on politics¹¹¹.

Any future measures taken regarding the HPV vaccine, including the imposition of vaccine mandates, should be formulated and advocated by public health officials and physicians, rather than politicians, on the basis of evidence derived from further testing and monitoring¹¹². Unfortunately, advocacy thus far by physician groups for widespread vaccination also has been tainted by industry pressures. Merck's relationship with multiple professional medical associations suggests that physicians' enthusiastic endorsements have been influenced by the

¹⁰⁷ Jones & Cook, *supra* note 20, at 29.

¹⁰⁸ Springen, *supra* note 11.

¹⁰⁹ Saul & Pollack, *supra* note 3.

¹¹⁰ These states are Alabama (H.B. 42), Arizona (S.B. 1437), Colorado (Co. Chapter No. 212 (2007)), Connecticut (H.B. 6085), Florida (S.B. 86), Georgia (H.B. 736), Hawaii (H.C.R. 51, H.B. 2141, S.B. 2124), Illinois (H.B. 2033), Indiana (Public Law No. 80 (2007)), Iowa (S.F. 43, S.F. 326, H.F. 611), Louisiana (H.B. 359), Maine (Maine Chapter No. 73 (2007)), Michigan (H.B. 5322, S.B. 415, S.B. 132, S.B. 415, S.B. 416), Minnesota (H.F. 1758, S.F. 1533), Missouri (S.B. 104), New Jersey (New Jersey Chapter No. 134 (2007)), New York (A. 3203, S. 1983, A.B. 2856, A.B. 7403), North Carolina (NC Session Law 2007-59), North Dakota (North Dakota Chapter No. 232 (2007)), Oklahoma (S.B. 1522), Pennsylvania (H.R. 21, H.R. 42, H.B. 845), Texas (H.B. 146, H.B. 1098, H.B. 1379), Utah (H.B. 358), Washington (Wash. Chapter No. 276 (2007)), and Wisconsin (A.B. 492, S.B. 252). National Conference of State Legislatures, *supra* note 66.

¹¹¹ Heidi M. Bauer & Kevin Ault, *Human Papillomavirus: Current Prevalence and Future Protection*, 33 SEXUALLY TRANSMITTED DISEASES 509, 510. (2006).

¹¹² Gostin & DeAngelis, *supra* note 9, at 1922.

substantial funding that Merck provided. Money and biased educational materials went to members of the American College of Obstetricians and Gynecologists, American Society for Colposcopy and Cervical Pathology, Society of Gynecologic Oncologists, and American College Health Association¹¹³.

Many articles discussing the negative reactions of parents, conservative groups, and religious groups to mandating vaccination against HPV point to parents' worry that receiving the vaccine will encourage teenage sexual activity or at least make teenage sexual activity appear acceptable¹¹⁴. However, studies have demonstrated that the availability of condoms and other prophylactics has not led to a rise in adolescent sexual activity¹¹⁵, an argument also used in favor of switching oral contraceptives – particularly those intended for emergency use – from by prescription only to over the counter status¹¹⁶. Furthermore, there are other factors that discourage teenagers from engaging in sexual activity, such as the possibility of becoming pregnant, contracting HIV, or the emotional and psychological effects that such behavior can have¹¹⁷. There is a subtle difference between the normative and positive implications of mandating HPV vaccination that has been overlooked in much of the literature. Requiring that all pre-adolescent girls receive Gardasil© is not a statement that adolescents should be sexually active but rather is a statement that adolescents will be sexually active. A mandate only makes sense if there is a level of inevitability inherent in the condition against which the vaccine is

¹¹³ Rothman & Rothman, *supra* note 42, at 783.

¹¹⁴ See Peres & Japsen, *supra* note 7; Peterson, *supra* note 7; *Merck Funds Effort to Pass Vaccine Laws*, *supra* note 7.

¹¹⁵ See R. Alta Charo, *Politics, Parents, and Prophylaxis – Mandating HPV Vaccination in the United States*, 356 THE NEW ENGLAND JOURNAL OF MEDICINE 1905, 1907 (2007); Steinbrook, *supra* note 22, at 1112.

¹¹⁶ Alastair Wood, Jeffrey Drazen, & Michael Greene, *A Sad Day for Science at the FDA*, 353 The New England Journal of Medicine 1197, 1198 (2005).

¹¹⁷ Kaiser 2005, *supra* note 27.

intended to protect¹¹⁸. Such inevitability appropriately may be attributed to the contraction of an illness such as measles or polio among unvaccinated individuals, but it seems to be less applicable to a volitional act such as sexual activity. Children often do not know why they receive the vaccines that they receive during various visits to the pediatrician throughout childhood. If little or no explanation is provided to children regarding why they are vaccinated against diphtheria or pertussis, then parents should not necessarily feel that they must discuss sexuality with their daughters when their daughters receive the HPV vaccine, an issue that often is raised in articles delineating reasons why parents oppose the mandate¹¹⁹. Given that sexuality is a frequent topic of conversation among junior high school students, and is portrayed throughout the media, it is unlikely that many parents will be successful in sheltering their daughters from any discussion of sexuality until well after the girls' eleventh or twelfth birthday. However, receipt of the HPV vaccine should not necessitate a discussion about sexual activity.

Therefore, it seems more likely that parents actually are angered by the assumption that has been made by the government; in effect, states proposing mandates have concluded that adolescent girls will be sexually active and therefore must be inoculated beforehand to protect them from themselves. Such a policy exceeds states' powers to set vaccine mandates, denies the variability among adolescent behavior, and places too much authority in parents' hands to determine what is appropriate sexual behavior for their daughters. In some instances, parents may not consent to their daughters receiving the HPV vaccine when it actually should be administered, given the daughters' choices regarding their future behavior. In other instances, parents who support vaccination against HPV may believe that their daughters should be

¹¹⁸ Charo suggests that such inevitability in fact exists. Charo, *supra* note 115, at 1907.

¹¹⁹ Haber et al., *supra* note 5, at 328.

vaccinated based on the parents' own views of reasonable sexual activity, regardless of their daughters' intentions. It would seem reasonable for a daughter in the latter category to interpret her parents' decision as a belief that adolescents will engage in sexual activity, a conviction that may conflict with the daughter's own moral, philosophical, or religious beliefs.

Of course, Merck would prefer that all females between the ages of 9 and 26 receive Gardasil®; consequently, the manufacturer is not going to encourage these individuals to think about whether they actually will need the vaccine based on their intended level of sexual activity. However, in its advertising campaign "One Less," Merck did take into consideration the importance of allowing minors to have a voice in the decision whether to get vaccinated, which their parents have the legal authority to make¹²⁰. In one television spot, highlighted in a New York Times article from 2007¹²¹, female adolescents engage in high-energy activities such as skateboarding, playing the drums, and playing basketball and soccer. These individuals are assertive and know how they want to protect themselves. After 23 seconds of the minute-long commercial, a middle-aged woman, ostensibly a mother, finally appears on the screen to describe the side effects of the vaccine¹²². It is clear that Merck is aiming its message directly at daughters in this advertisement. In contrast, a second English-language television commercial and a Spanish-language commercial focus on racially diverse mother-daughter relationships. The Spanish-language advertisement portrays mothers and daughters shopping for clothes and participating in cultural performances and other artistic activities¹²³. Likewise, the second English-language advertisement portrays happy, active women and their daughters engaging in

¹²⁰ Jennifer L. Rosato, *Let's Get Real: Quilting a Principled Approach to Adolescent Empowerment in Health Care Decision-Making*, 51 DEPAUL L. REV. 769, 771 (2002).

¹²¹ Claire Dederer, *Pitching Protection, to Both Mothers and Daughters*, N.Y. TIMES, Feb. 18, 2007, at 34.

¹²² This advertisement is available on YouTube: <http://www.youtube.com/watch?v=hJ8x3KR75fA>

¹²³ This advertisement is available on YouTube: <http://www.youtube.com/watch?v=f66nM-UbQQc&feature=related>

similar activities¹²⁴. A third English-language advertisement features eight confident, independent young women who all appear to be in their twenties and who suggest that the viewer get vaccinated as they did¹²⁵.

There is no mention of sex in any of these four commercials, and no men appear in the advertisements, aside from an image of a father that remains on the screen for a second or two in the first English-language commercial. Anyone who views these commercials and does not already know the source of HPV will not be able to determine its mode of transmission from the advertisements. Thus, these television spots avoid any suggestion that receipt of the vaccination will encourage promiscuity. However, by focusing on the prevention of cervical cancer, rather than its precursors or the behavior that leads to exposure, the advertisements also suggest that the vaccine is necessary for all girls. Rothman and Rothman suggest that such a marketing ploy is ethically inappropriate¹²⁶, while Jones and Cook explicitly state that it is unwise¹²⁷. The “One Less” campaign clearly was geared towards females only, but pre-adolescent and adolescent males also are expected to become a target audience. Jones and Cook found that males understandably are more likely to accept a vaccine that is promoted as protecting against both genital warts and cervical cancer, rather than a vaccine that prevents only cervical cancer¹²⁸. Nevertheless, Gardasil© won pharmaceutical marketing and advertising awards¹²⁹.

¹²⁴ This advertisement is available on YouTube: <http://www.youtube.com/watch?v=15Jk3OBm3lU&feature=related>

¹²⁵ This advertisement is available on YouTube:
<http://www.youtube.com/watch?v=ZHUamYNSh9c&feature=related>

¹²⁶ Rothman & Rothman, *supra* note 42, at 781-82.

¹²⁷ Jones & Cook, *supra* note 20, at 28.

¹²⁸ *Id.*

¹²⁹ See Rothman & Rothman, *supra* note 42, at 781; Rosenthal, *supra* note 13.

ABILITY TO ENFORCE MANDATORY VACCINATION

Under the Tenth Amendment to the United States Constitution, the states are granted police powers, which include protection of the public health and welfare¹³⁰. Although vaccines are approved and recommended at the federal level, states can determine which vaccinations must be administered to individuals at various ages; states often look to these federal recommendations when instituting vaccination requirements¹³¹. Therefore, states can establish school vaccination mandates for those vaccines the receipt of which is deemed to be a necessary precondition to entering a particular grade in school. For example, according to the National Vaccine Advisory Committee (NVAC) of the Department of Health and Human Services, as of 2005-2006, 21 states required receipt of the tetanus and diphtheria vaccine, 47 states required receipt of the measles vaccine, 33 states required receipt of the hepatitis B vaccine, and 24 states required receipt of the varicella vaccine before entering junior high school¹³².

However, the Supreme Court has set limits on the types of diseases that can serve as the basis for a mandatory vaccination law. Literature discussing the constitutional validity of the HPV vaccine mandate relies heavily on Jacobson v. Massachusetts, 197 U.S. 11 (1905), in which the Supreme Court first delineated the requirements for a valid vaccination mandate; here, the disease at issue was smallpox¹³³. The exercise of state police powers must be reasonable, justified by the circumstances, and intended to protect the community rather than only the

¹³⁰ Kochuba, *supra* note 1, at 764.

¹³¹ National Conference of State Legislatures, *supra* note 66; Bridget M. Kuehn, *CDC Panel Backs Routine HPV Vaccination*, 296 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 640, 641 (2006).

¹³² National Vaccine Advisory Committee, *Mandates for Adolescent Immunizations: Recommendations from the National Vaccine Advisory Committee*, 35 AMERICAN JOURNAL OF PREVENTIVE MEDICINE 145, 146 (2008).

¹³³ See e.g. Micah Globerson, *Gardasil a Year Later: Cervical Cancer as a Model for Inequality of Access to Health Services*, 15 CARDOZO J.L. & GENDER 247, 256 (2009); Kochuba, *supra* note 1, at 764-65; Gendel, *supra* note 82, at 276-79.

recipient of the vaccine, a condition now known as herd immunity, for the court to uphold this form of impingement of individual liberty. Jacobson, 197 U.S. at 27-29. Zucht v. King, 260 U.S. 174, 176 (1922), extended Jacobson to apply to school vaccination mandates. In the later case In re Christine M., 595 N.Y.S.2d 606, 613, 618 (N.Y. Fam. Ct. 1992), the Court emphasized that for a vaccine to be mandated, it also must be necessary. Some authors deem this condition to be lacking in the case of HPV due to the low incidence of harm, slow rate of disease development, and volitional mode of transmission, among other factors¹³⁴.

HPV variably is compared to polio, smallpox, and measles throughout the literature. Each of these illnesses has been virtually eradicated through mandatory vaccines, but none provides an appropriate analogy to HPV¹³⁵. Polio, smallpox, and measles are highly contagious diseases that can spread rapidly through the public and kill many individuals. By vaccinating nearly everyone against these scourges, the United States has achieved herd immunity against each. Even if an unvaccinated individual is present in the population, the vast majority of individuals have been vaccinated; as a result, the unvaccinated individual is not at risk of contracting a disease that cannot spread. Some articles discussing whether an HPV vaccine mandate is appropriate state that such a vaccination eventually will lead to herd immunity¹³⁶, while others assert that the vaccine is intended to protect only the recipient¹³⁷, and therefore is not the proper focus of a vaccine mandate. In addition, since Gardasil© only protects against a subset of HPV types, widespread vaccination could not achieve complete herd immunity¹³⁸. Even if it is theoretically possible to achieve herd immunity against some forms of HPV, another divide in the literature

¹³⁴ Baron, *supra* note 103, at 150-51.

¹³⁵ Gostin & DeAngelis, *supra* note 9, at 1922; Gendel, *supra* note 82, at 276-79.

¹³⁶ Larkin, *supra* note 7.

¹³⁷ Charo, *supra* note 115, at 1906; Gendel, *supra* note 82, at 286.

¹³⁸ De Soto, *supra* note 54, at 268.

arises regarding whether it is reasonable – scientifically or constitutionally – to mandate vaccination for girls only, or if boys must be vaccinated as well to achieve such immunity at the population level¹³⁹ and avoid Equal Protection Clause violations¹⁴⁰. Gardasil© is the first vaccine to be the subject of a mandate that applies only to one gender¹⁴¹. Cervical cancer afflicts only females, but males and females are equally vulnerable to HPV infection, and most females contract HPV from their male sexual partners¹⁴². Since vaccination of males may be indicated, and Gardasil© has been approved for use in males, it appears that waiting to push for vaccination mandates until these mandates reasonably could have been applied to both genders would have avoided this part of the conflict and also cut in half the amount of time and effort necessary to deal with the legislative process¹⁴³. Although this paper focuses on the ability of pre-adolescent and adolescent females to make their own competent medical decisions, the same arguments apply to pre-adolescent and adolescent males.

In addition to the absence of a public health necessity that could justify any form of HPV vaccine mandate, many commentators point to the lack of a reasonable relationship between vaccination against HPV and school attendance. Unlike airborne illnesses, HPV cannot be transmitted through normal, casual classroom contact. There is no inherent connection between the spread of HPV and school attendance¹⁴⁴. Admittedly, a school vaccine mandate likely will be more successful, in terms of rate of vaccine uptake, than a voluntary policy and educational

¹³⁹ See Manhart et al., *supra* note 19, at 507; Globerson, *supra* note 133, at 256.

¹⁴⁰ See Baron, *supra* note 103, at 151, discussing Wong Wai v. Williamson, 103 F. 1 (N.D. Cal. 1900); Javitt et al., *supra* note 45, at 392; Kochuba, *supra* note 1, at 781-82.

¹⁴¹ Javitt et al., *supra* note 45, at 384.

¹⁴² Globerson, *supra* note 133, at 256-57.

¹⁴³ National Vaccine Advisory Committee, *supra* note 132, at 148.

¹⁴⁴ See Javitt et al., *supra* note 45, at 389-90; Ross D. Silverman, *Litigation, Regulation, and Education – Protecting the Public's Health through Childhood Immunization*, 360 THE NEW ENGLAND JOURNAL OF MEDICINE 2500, 2501 (2009).

campaign¹⁴⁵. The NVAC, among others, bemoans the infrequency with which adolescents seek and receive preventive medical care, which presents an obstacle to widespread vaccine administration¹⁴⁶. However, even students who are not at risk of contracting HPV as a result of their behavioral choices could be excluded from school if they are not vaccinated, according to the provisions in several states' proposed legislation.

Implementing an HPV vaccine mandate as a condition for school attendance also has been challenged as an illegal intrusion into parents' rights to raise their children, a view with which the American College of Pediatricians agrees¹⁴⁷. Parents have a fundamental due process right under the Fourteenth Amendment to make decisions regarding upbringing without interference by the state¹⁴⁸. This right is limited, however, when the decision at issue could lead to substantial harm to the children or other individuals, in which case the state may exercise its *parens patriae* authority to intervene on behalf of the child¹⁴⁹. Clearly, such harm would not occur if parents, or preferably the pre-adolescents or adolescents themselves, chose to reject vaccination against HPV. An individual can avoid contracting HPV by behaving in a particular manner. Even if the individual engages in sexual activity, she will not necessarily contract HPV. Furthermore, most HPV infections are asymptomatic, and of those cases that do lead to symptoms, most will not lead to cancer. A decision not to vaccinate will not lead to irreparable

¹⁴⁵ Colgrove, *supra* note 18, at 2390-91.

¹⁴⁶ National Vaccine Advisory Committee, *The Promise and Challenge of Adolescent Immunization*, 35 AMERICAN JOURNAL OF PREVENTIVE MEDICINE 152, 153(2008).

¹⁴⁷ Peres & Japsen, *supra* note 7.

¹⁴⁸ See Gendel, *supra* note 82, at 284-85, citing *Troxel v. Granville*, 530 U.S. 57 (2000); Christine M. Hanisco, *Acknowledging the Hypocrisy: Granting Minors the Right to Choose Their Medical Treatment*, 16 N.Y.L. SCH. J. HUM. RTS. 899, 903-04 (2000), citing *Pierce v. Society of Sisters*, 268 U.S. 510 (1925), and *Meyer v. Nebraska*, 262 U.S. 390 (1923).

¹⁴⁹ See Gendel, *supra* note 82, at 284-85, and Hanisco, *supra* note 148, at 904-06, both citing *Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944).

harm either to the individual who would be receiving the vaccine or to her peers. Thus, there is no danger that must be avoided by ordering receipt of a vaccination of which parents do not approve¹⁵⁰. Nevertheless, it is possible that the force and speed with which mandates have been proposed – and two successfully have been enacted – may cause parents to feel pressured to have their daughters vaccinated¹⁵¹. Throughout the debate regarding parents' right to make decisions, little attention has been paid to the individuals who will be affected most by the decision: the daughters.

PRE-ADOLESCENT AND ADOLESCENT COMPETENCY TO MAKE MEDICAL DECISIONS

In general, parents have the authority to grant or withhold consent to the voluntary medical treatment of their minor offspring¹⁵². However, in addition to setting the age of majority and the age at which minors can enter into contracts, most states also establish the age at which minors can consent to medical treatment or the conditions under which they can consent to such treatment regardless of age. Typical conditions include whether the minor is married, in the military, or emancipated¹⁵³. These minimum age requirements often do not deal with withholding consent, an issue that is particularly important in the context of a mandate. These requirements also are separate from provisions governing the ability to opt-out of receiving a mandatory vaccination. Mandatory vaccination rules limiting to parents and guardians the ability to opt-out of receiving the vaccine may be appropriate regarding vaccines that protect against severe airborne illnesses. Minors are unable to avoid airborne illnesses through typical classroom

¹⁵⁰ Gendel, *supra* note 82, at 286-88.

¹⁵¹ Rosenthal, *supra* note 13.

¹⁵² Rosato, *supra* note 120, at 771.

¹⁵³ *Id.* at 776-77.

behavior, so there is no personal choice involved in whether an individual contracts the illness at issue. However, such rules should be applied only to vaccines unrelated to sexual activity.

An evaluation of the states' laws regarding the minimum age of consent to medical treatment reveals an apparent consensus that consent regarding issues related to sexual activity is different from consent regarding other ailments and conditions. Many states provide separate provisions specifically governing consent for the diagnosis, treatment, and prevention of VDs and STDs; these provisions often do not set a minimum age for providing consent and do not require parental notification or approval. For example, Kansas has at least three statutory sections governing medical consent by minors: an unmarried and pregnant minor may give consent to medical treatment regardless of age¹⁵⁴, a minor above the age of 16 may give consent to medical treatment¹⁵⁵, and any minor may give consent with regard to the diagnosis and treatment of a VD¹⁵⁶. Similarly, in Oregon, an individual above the age of 15 may consent to medical treatment, and a minor of any age may consent to the diagnosis and treatment of a VD¹⁵⁷. In Texas, an individual above the age of 16 who is living apart from his or her parents and managing his or her own finances may give valid consent, but any minor regardless of age may consent to treatment for an infectious disease¹⁵⁸. Alabama¹⁵⁹, Alaska¹⁶⁰, Arizona¹⁶¹, DC¹⁶², Hawaii¹⁶³, Indiana¹⁶⁴, Louisiana¹⁶⁵, Maine¹⁶⁶, Maryland¹⁶⁷, Michigan¹⁶⁸, Minnesota¹⁶⁹,

¹⁵⁴ K.S.A. 38-123

¹⁵⁵ K.S.A. 38-123b

¹⁵⁶ K.S.A. 65-2892

¹⁵⁷ O.R.S. § 109.640

¹⁵⁸ V.T.C.A., Family Code § 32.003

¹⁵⁹ Ala. Code 1975 § 22-8-6

¹⁶⁰ AS § 25.20.025

¹⁶¹ A.R.S. § 44-132.01

¹⁶² 22 DCMR § 600.7

¹⁶³ Haw. Rev. Stat. § 577A-2

¹⁶⁴ IC 16-36-1-3

Missouri¹⁷⁰, Montana¹⁷¹, Nevada¹⁷², New Jersey¹⁷³, North Carolina¹⁷⁴, Oklahoma¹⁷⁵, South Dakota¹⁷⁶, and Virginia¹⁷⁷ allow minors of any age to consent to treatment related to a VD. Additionally, California¹⁷⁸, Idaho¹⁷⁹, Illinois¹⁸⁰, North Dakota¹⁸¹, and Vermont¹⁸² set minimum age limits for the provision of medical consent regarding diagnosis, treatment, and prevention of a VD well below 18. The law in Arkansas also reflects a form of the mature minor exception; any minor who is “sufficiently intelligent to understand the consequences” of the medical treatment requested may consent¹⁸³. Admittedly, vaccination against HPV is intended to prevent, not treat, an STI. However, states have recognized not only that rules regarding VDs should be separate from those regarding other forms of medical care, but also that minors are competent to make decisions regarding treatment for a VD. In terms of prevention, Colorado¹⁸⁴, Hawaii¹⁸⁵, Maryland¹⁸⁶, Oregon¹⁸⁷, Tennessee¹⁸⁸, and Virginia¹⁸⁹ permit minors of any age to request and

¹⁶⁵ LA R.S. 40 § 1095

¹⁶⁶ 22 M.R.S.A. § 1823; 32 M.R.S.A. §§ 2595, 3292

¹⁶⁷ MD Code, Health - General, § 20-102

¹⁶⁸ M.C.L.A. 333.5127

¹⁶⁹ M.S.A. § 144.343

¹⁷⁰ V.A.M.S. 431.061

¹⁷¹ MCA 41-1-402

¹⁷² N.R.S. 129.060

¹⁷³ N.J.S.A. 9:17A-4

¹⁷⁴ N.C.G.S.A. § 90-21.5

¹⁷⁵ 63 Okl. St. Ann. § 2602

¹⁷⁶ SDCL § 34-23-16

¹⁷⁷ Va. Code Ann. § 54.1-2969(E)

¹⁷⁸ West's Ann. Cal. Fam. Code § 6926

¹⁷⁹ I.C. § 39-3801

¹⁸⁰ 410 ILCS 210/4

¹⁸¹ NDCC, 14-10-17

¹⁸² 18 V.S.A. § 4226

¹⁸³ A.C.A. § 20-9-602

¹⁸⁴ C.R.S.A. § 13-22-105

¹⁸⁵ Haw. Rev. Stat. § 577A-2

¹⁸⁶ MD Code, Health - General, § 20-102

¹⁸⁷ O.R.S. § 109.610

receive information and services related to birth control and family planning. Moreover, a minor need not notify her parents or obtain their consent before buying condoms or other over-the-counter contraceptives¹⁹⁰. Minors' use of contraceptives and its relation to unwanted pregnancies and abortions entail a host of other complicated issues. Nevertheless, the apparent determination by some states that minors are capable of making informed, competent decisions about contraceptives signals a belief that personal choice is a necessary element of sexual behavior.

Legal commentators state that the separation of sexually-related medical issues from other medical conditions within the realm of consent rules cannot be taken as evidence of a belief by states that adolescents actually are competent to make decisions regarding their medical care for sexually-related medical issues. Instead, rules allowing minors to consent to their own treatment for VD's were enacted to provide minors with the privacy that was considered necessary for minors to seek out treatment for these conditions. State governments were concerned that VD's would spread more widely if minors were required to notify their parents or obtain their parents' consent before receiving treatment for VD's, because minors were more likely to avoid medical treatment altogether if such a requirement were in place. Thus, adolescents are deemed mature in this narrow context out of necessity, rather than as a result of any true belief that adolescents are capable of making such decisions¹⁹¹. Given the growing body of psychological literature supporting the competency of pre-adolescents and adolescents to make medical decisions, it seems reasonable that the rules at issue could be endowed with an additional justification even if that were not the original justification. Studies of adolescents'

¹⁸⁸ T. C. A. § 68-34-107

¹⁸⁹ Va. Code Ann. § 54.1-2969(E)

¹⁹⁰ Paul Arshagouni, "*But I'm an Adult Now...Sort Of*": Adolescent Consent in Health Care Decision-Making and the Adolescent Brain, 9 J. HEALTH CARE L. & POL'Y 315, 325 (2006).

¹⁹¹ See Rosato, *supra* note 120, at 778; Hanisco, *supra* note 148, at 912.

decision-making capabilities only support the wisdom of these rules regarding consent for treatment for VD. Furthermore, allowing pre-adolescents and adolescents to grant or withhold consent for vaccination against HPV would support both the privacy-based rationale and the competency-based rationale that can be assigned to these rules. Assuming that the rules are based on privacy, allowing minors whose parents do not want them to be vaccinated to consent to receipt of the vaccine without needing to notify their parents or obtain their parents' consent would support the public health goal of preventing the spread of STIs. Conversely, allowing minors whose parents want them to be vaccinated to withhold consent because they do not need the vaccine also would promote the privacy of individuals who may feel pressured by their parents to behave in a manner with which they do not agree but who do not feel comfortable discussing with their parents their decision not to engage in sexual activity.

The ages set for considering an individual an adult, or at least competent to make specific types of decisions, often appear to be arbitrary. For instance, California¹⁹², Illinois¹⁹³, and Vermont¹⁹⁴ allow minors above the age of 12 to consent to medical care related to the diagnosis and treatment of an STD, while Idaho¹⁹⁵ and North Dakota¹⁹⁶ set 14 as the appropriate age. Similarly, a variety of ages have been set as appropriate minima for drinking, driving, and viewing an R-rated movie, for example. However, when the psychological capabilities of pre-adolescents and adolescents are evaluated, varying age limits associated with different activities appear more logical¹⁹⁷.

¹⁹² West's Ann. Cal. Fam. Code § 6926

¹⁹³ 410 ILCS 210/4

¹⁹⁴ 18 V.S.A. § 4226

¹⁹⁵ I.C. § 39-3801

¹⁹⁶ NDCC, 14-10-17

¹⁹⁷ Catherine Rampell, *How Old is Old Enough?*, N.Y. TIMES, Nov. 15, 2009, at 5.

The American Psychological Association (APA) recently came under fire as a result of its apparently inconsistent views on the maturity of adolescents. The APA authored an amicus brief in the Supreme Court case Hodgson v. Minnesota, 497 U.S. 417 (1990), in which the APA argued that adolescents' mature cognitive abilities make them capable of making an independent decision to have an abortion, even at age 14. Specifically, the APA stated that 14-year-olds are capable of "understanding treatment alternatives [and] considering risks and benefits"¹⁹⁸. Several years later, the APA asserted in its amicus brief in the Supreme Court case Roper v. Simmons, 543 U.S. 551 (2005), that adolescents' emotional and social immaturity militate against allowing the death penalty for juveniles at age 16 or 17¹⁹⁹.

In an effort to demonstrate the consistency of these apparently incongruent arguments, Steinberg et al. present and discuss data supporting the APA's overarching view that adolescents' cognitive abilities mature faster than their emotional and social abilities. During adolescence, an individual may be as mature as an adult with regard to consideration of moral issues but still may lag far behind adults in terms of impulsivity and vulnerability to peer pressure. As a result, it is appropriate to treat adolescents as adults in some contexts but not in others. Cognitive abilities are deemed to be fully matured by age 16, but adolescents' emotional and social abilities are not equivalent to those of adults even at age 18. The authors point out that many adolescents who consider obtaining an abortion without their parents' knowledge seek advice from an adult such as a teacher, counselor, or member of the clergy. In many states,

¹⁹⁸ Brief for American Psychological Association as Amicus Curiae, Ohio v. Akron Center for Reproductive Health, Inc., 497 U.S. 502 (1990) and Hodgson v. Minnesota, 497 U.S. 417 (1990), quoted in Laurence Steinberg, Elizabeth Cauffman, Jennifer Woolard, Sandra Graham, & Marie Banich, *Are Adolescents Less Mature Than Adults? Minors' Access to Abortion, the Juvenile Death Penalty, and the Alleged APA "Flip-Flop"*, 64 AMERICAN PSYCHOLOGIST 583, 584 (2009). [hereinafter Steinberg et al.]

¹⁹⁹ Brief for American Psychological Association as Amicus Curiae, Roper v. Simmons, 543 U.S. 551 (2005), cited in Steinberg et al., *supra* note 198, at 584.

women who are seeking an abortion must receive counseling before obtaining the procedure, and some states impose a waiting period between the receipt of counseling and the initiation of the procedure to allow the prospective patients to consider their options in an informed manner.

Steinberg et al. emphasize the importance of allowing individuals to receive information and take time to think about the information before making this medical decision, which also is relevant in the debate over receiving the HPV vaccine. In the context of medical decision making in general, individuals often have the opportunity to engage in “deliberative, reasoned decision making” and converse with “consultants [health care practitioners] who can provide objective information about the costs and benefits of alternative courses of action”²⁰⁰. Furthermore, the authors state that the adults involved in consulting with the adolescent who must make the medical decision “cannot and should not make the decision for the adolescent”²⁰¹. Whether this individual is a health care practitioner, parent, or other adult, Hartman concurs that adolescents benefit from having the opportunity to converse with an adult whom the adolescent trusts before making a treatment regarding medical care²⁰².

Providing pre-adolescent and adolescent girls with the opportunity to learn about HPV and the options they have for avoiding infection is both consistent with the girls’ capabilities and supports their autonomy. Steinberg and Cauffman delineate in their literature review on adolescent maturity of judgment three categories of psychosocial factors that influence decision making. One of these categories is responsibility, which includes autonomy. Disagreeing with standard definitions of autonomy that focus on independent decision making, the authors state

²⁰⁰ Steinberg et al., *supra* note 198, at 592.

²⁰¹ *Id.*

²⁰² Rhonda Gay Hartman, *Adolescent Decisional Autonomy for Medical Care: Physician Perceptions and Practices*, 8 U. CHI. L. SCH. ROUNDTABLE 87, 99 (2001).

that individuals who have developed mature judgment “know[] where to turn for advice, know[] how to solicit it, and know[] whether and to what extent to follow it”²⁰³. This ability improves throughout adolescence.

However, other research suggests that children even as young as 9 can provide a competent voice in their own medical decisions. Weithorn and Campbell sought to determine and compare the level of competence to make medical decisions demonstrated by individuals ages 9, 14, 18, and 21. Four aspects of competency were measured: ability to make a choice among alternative possible treatments, reasonable outcome, rational reasoning that contributed to the choice made, and understanding of risks and benefits. Understanding was subdivided into comprehension of the facts of the situation and appreciation of the consequences of the choice on the individual. As it was defined here, competency requires formal operational thought, which develops in children growing up in Western cultures between ages 11 and 14. As the authors had hypothesized, 14-year-olds were as competent as adults on all four aspects of competency. While 9-year-olds had more difficulty demonstrating rational reasoning that contributed to the choice made and an understanding of risks and benefits, these children were competent regarding ability to make a choice and a reasonable outcome of that choice²⁰⁴. Therefore, even if ACIP states, and researchers conducting cost-effectiveness studies advocate²⁰⁵, that 11- and 12-year-old girls are the proper recipients of the HPV vaccine, it would be more appropriate to allow these girls to participate in the decision making process regarding whether they should receive the vaccine.

²⁰³ Laurence Steinberg & Elizabeth Cauffman, *Maturity of Judgment in Adolescence: Psychosocial Factors in Adolescent Decision Making*, 20 LAW AND HUMAN BEHAVIOR 249, 254 (1996).

²⁰⁴ Lois A. Weithorn & Susan B. Campbell, *The Competency of Children and Adolescents to Make Informed Treatment Decisions*, 53 CHILD DEVELOPMENT 1589 (1982).

²⁰⁵ Morton, *supra* note 99. The assumptions used as the basis for this cost-effectiveness analysis have been challenged as excessively optimistic. *Human Papillomavirus Vaccination – Reasons for Caution*, 359 THE NEW ENGLAND JOURNAL OF MEDICINE 861, 862 (2008).

The findings reported in developmental psychology literature are consistent with the views of healthcare providers who interact with adolescent patients. Hartman surveyed 173 pediatricians, family practitioners, and internists about their perceptions of adolescent patients. Most of these physicians agreed that these patients “understand information about medical treatment and conditions, engage in rational deliberation during the decisional process, and communicate choices and concerns clearly”²⁰⁶, all of which are factors that Weithorn and Campbell addressed directly in their study of the abilities of pre-adolescents and adolescents. Hartman’s data reflect the opinions of physicians who have evaluated their cumulative experiences retrospectively, rather than being asked to respond to survey items during real-time, individual interactions. However, Hartman’s data are valuable because they describe adolescent behavior in the relevant environment. This study suggests that adolescents are capable of making competent medical decisions not only in the context of depersonalized hypothetical scenarios but also in the more stressful setting of a doctor’s office.

Literature on HPV vaccination often does not consider that the views of parents may conflict with the views of their daughters. When authors do confront such a dilemma, they assume that parents would not want their daughters to receive the vaccination while the girls actually would want to be vaccinated. For instance, Balog asserts that “the right of the child to receive the preventive measure should override respect for the parents’ autonomy and the parents’ desire to teach social beliefs that restrict health care action, because the health threat directly involves the life of the child”²⁰⁷. This argument supports the ability of the pre-adolescent or adolescent female to choose whether to receive the vaccination, but it also goes too far. Some

²⁰⁶ Hartman, *supra* note 202, at 103.

²⁰⁷ Joseph E. Balog, *The Moral Justification for a Compulsory Human Papillomavirus Vaccination Program*, 99 AMERICAN JOURNAL OF PUBLIC HEALTH 616, 618 (2009).

targeted recipients likely will not want to receive the vaccine or feel that they do not need it, given the choices they intend to make regarding their level of sexual activity, but their parents will support vaccination. In states where vaccination has been mandated, the parents' views carry little weight. However, in states where vaccination has not yet been mandated, parents will be able to decide whether their daughters should be vaccinated, regardless of their daughters' views.

Bills that suggest that information about HPV and cervical cancer be promulgated, rather than immediately mandating receipt of the HPV vaccine, are preferable for a number of reasons. Conflict between the state and parents who feel that their rights are being threatened will be minimized, many individuals will increase their knowledge about an important public health issue, and students will be allowed to continue to attend school while individual families consider the costs and benefits of vaccination. However, it is important to consider to whom the information is being directed²⁰⁸. In formulating its advertising strategy, Merck understood that in states without mandates, the company needed to convince pre-adolescent and adolescent girls that they would benefit from the vaccine. Once members of this targeted audience became supporters of Merck's campaign, they would request their parents' consent to receive Gardasil®. Admittedly, Merck's motives likely were more commercial than benevolent. However, an examination of the bills proposed in legislatures across the country suggests that many of the states did not similarly recognize the importance of educating the individuals who actually would be receiving the vaccine. Instead, states such as Colorado²⁰⁹, Florida²¹⁰, Georgia²¹¹, Hawaii²¹²,

²⁰⁸ National Vaccine Advisory Committee, *supra* note 146, at 155.

²⁰⁹ S.B. 80

²¹⁰ S.B. 86, S.B. 660

²¹¹ H.B. 736

²¹² H.C.R. 51, H.B. 2141, S.B. 2124

Illinois²¹³, Indiana²¹⁴, Kansas²¹⁵, Minnesota²¹⁶, Missouri²¹⁷, New Jersey²¹⁸, New Mexico²¹⁹, New York²²⁰, North Carolina²²¹, and Washington²²² indicated that new educational materials discussing HPV and cervical cancer should be directed to parents and guardians²²³. Neglecting to provide educational materials to pre-adolescent and adolescent girls belies the girls' ability to understand and denies them the opportunity to learn directly about medical issues that affect them. As the NVAC emphasizes, gearing information directly towards adolescents is especially important in the case of a vaccine intended to protect partially – but not fully – against an STI, since recipients of the vaccine must be warned that they still will need to rely on other forms of protection. Moreover, informational materials aimed at adolescents likely will need to adopt a different tone from those aimed at parents and guardians²²⁴.

Legal literature on the competency of minors to make decisions regarding their own medical treatment generally does not discuss vaccination policy but rather focuses on voluntary interventions for conditions that afflict an individual rather than those that have the potential to harm a community. Since these opt-in therapies require parental consent, the authors can analyze whether it is appropriate to require such consent regardless of the type of treatment at issue, or if minors should be allowed to exert some influence over their own treatment in some

²¹³ H.B. 115

²¹⁴ Public Law No. 80 (2007)

²¹⁵ H.B. 2227

²¹⁶ H.F. 1758, S.F. 1533, S.F. 243

²¹⁷ S.B. 104, H.B. 802, S.B. 514

²¹⁸ New Jersey Chapter No. 134 (2007)

²¹⁹ S.B. 244, S.B. 1174

²²⁰ A.B. 7403

²²¹ NC Session Law 2007-59

²²² Wash. Chapter No. 276 (2007)

²²³ But see Colorado Co. Chapter No. 212 (2007), Iowa S.F. 43 and H.F. 611, and New York A.B. 2856, all of which proposed including information about HPV and cervical cancer in the sexual education curriculum in schools.

²²⁴ National Vaccine Advisory Committee, *supra* note 146, at 155.

circumstances. This paper focuses on a treatment for which parents already must – or likely soon will need to – opt out in some states, but which is voluntary in other jurisdictions. Therefore, the arguments presented in the legal literature also can be applied to the Gardasil© vaccination policies. Relying on research in the field of developmental psychology to support their conclusions, Arshagouni, Austin, Hanisco, Hartman, and Rosato all advocate a shift in the law that would grant more authority to minors over their own medical treatment. These authors point to a growing body of work in both the legal and medical arenas that push for similar proposals.

Arshagouni would divide medical procedures into two categories: those that are routine and low-risk without potential adverse long-term consequences, and those that are high-risk or have potential adverse long-term consequences. He would grant a “presumption of capacity” to make decisions among adolescents with regard to the former, and a “rebuttable presumption of no decisional capacity” with regard to the latter²²⁵. The author emphasizes not only the progress that has been made in scientific understanding of the ability of adolescents to comprehend medical dilemmas, but also the importance of allowing adolescents to develop the ability to make decisions based on that comprehension. He states that removing reasonable opportunities for adolescents to exercise decision-making capacity “inhibits development” of these skills²²⁶. As a result, adolescents’ current abilities are denied and their future capabilities may be stunted. Arshagouni and Hartman both explain that the promotion of healthy brain development and an attitude of self-efficacy and self-respect among a generation of adolescents who will need to grow into confident and competent adults require giving these adolescents the opportunity to make decisions within the context of routine medical care.

²²⁵ Arshagouni, *supra* note 190, at 359.

²²⁶ *Id.* at 361.

Arriving at a similar conclusion regarding the types of medical procedures for which minors should be able to provide their own consent, Austin evaluates a variety of psychological studies. Acknowledging that competency develops in different contexts at different rates, Austin rejects the “all-or-nothing standard” imposed by law as inconsistent with psychological reality²²⁷. As Weithorn and Campbell indicated, courts consider several elements when making competency determinations, such as a basic ability to communicate, recognition of the current situation, comprehension of possible treatments, and an understanding of consequences of those options. Summarizing the data, Austin states that adolescents age 14 and older demonstrate adult-level competence with regard to these factors in the context of medical treatment.

According to Hanisco, physicians who often have minor patients disagree with the current law on consent to such a degree that the American Academy of Pediatrics Task Force has promulgated guidelines on this subject. The guidelines suggest that a physician should obtain the written consent of a minor age 13 or older for elective surgery or other treatment, and a minor over age 7 also should be included in the decision-making process. Pediatricians should conduct individualized assessments of the patient’s capabilities in relation to the severity of the condition and risks and benefits of the treatment options when deciding whether a minor over age 7 reasonably can understand the decision that must be made²²⁸. These guidelines are consistent with behavior noted by Hartman in her study of physicians’ perception of adolescents’ abilities, discussed above. Specifically, Hartman states that many pediatricians believe that “the law should defer to medical judgment about adolescent decisional capacity.” In other words, instead

²²⁷ Anthony W. Austin, *Medical Decisions and Children: How Much Voice Should Children Have in Their Medical Care?*, 49 ARIZ. L. REV. 143, 160 (2007).

²²⁸ American Academy of Pediatrics, *Task Force on Pediatric Research, Informed Consent, and Medical Ethics, Consent*, 57 PEDIATRICS 414, 415 (1976), cited in Hanisco, *supra* note 148, at 922.

of allowing the law to impose a blanket presumption of incompetence from the outside, pediatricians would prefer to have the independence to make individualized assessments of pre-adolescent and adolescent competence within the practice of medicine; such assessments likely would establish the competence of many of these patients.

Although Rosato is not as generous as other authors in terms of arguing for the provision of decision making authority to minors in the context of “ordinary health care decisions”²²⁹ (as compared to abortion, “life-sustaining treatment decisions,” and “decisions with no direct physical benefit to the child,” none of which is at issue here), she does advocate for a “participatory model”²³⁰. The minor should be included in the process because doing so would promote “competence and moral development”²³¹. Echoing Hartman, Rosato also states that “allowing adolescents to make health care decisions is beneficial because it is likely to improve their self-esteem and sense of control in the short-term, and make them better decision-makers and citizens in the long-term”²³². Rosato also asserts that “the failure to respect adolescents’ burgeoning autonomy is likely to cause harm to their personhood, especially when the health care decision involves the exercise of moral judgment”²³³; this statement that is particularly relevant in the context of a medical issue related to sexuality.

ALTERNATIVE COURSES OF ACTION

Merck likely could have avoided much of the negative press that it received in relation to the promotion of Gardasil© if it had adopted an alternative strategy. Merck’s push to make HPV vaccination mandatory soon after the vaccine was approved by the FDA alienated both the

²²⁹ Rosato, *supra* note 120, at 801-02.

²³⁰ *Id.* at 803.

²³¹ *Id.*

²³² *Id.* at 790.

²³³ *Id.*

parents of targeted girls and the physicians who would be expected to administer the vaccine. In states where vaccination has not been mandated, physicians have been reluctant to encourage parents to allow their pre-adolescent and adolescent girls to receive the vaccine, out of fear of parents' responses²³⁴. Certainly, a successful mandate would create automatically a large market for Merck's vaccine. However, providing girls with the choice of whether to get the vaccine through an opt-in system likely could have avoided the outrage over the mandate that occurred in some states and still have led to financial success for Merck.

Girls who have been educated about the prevalence of HPV, the link between HPV and cervical cancer, and the protection that a vaccination against HPV can provide are more likely to voluntarily seek vaccination than girls who are not as knowledgeable about these issues. Within their sample, Jones and Cook found that 77.5% of male college students and 88.6% of female college students were willing to receive an HPV vaccine. Both level of knowledge about HPV and level of self-reported sexual activity were significantly related to intent to receive the vaccine. Specifically, students who had had sex, and students who reported having more than five sexual partners, were significantly more likely to indicate an intention to receive the vaccine than their sexually inexperienced peers²³⁵. On the one hand, these data can be interpreted to suggest that sexually inexperienced adolescents and young adults, once they have received more education regarding HPV, also will be eager to receive the vaccine, as Jones and Cook suggest. On the other hand, the same data simply could reflect the students' self-awareness regarding their future sexual behavior. A student who does not intend to become sexually active in college may not feel the need to receive the vaccine regardless of the amount of educational material that

²³⁴ Peres & Japsen, *supra* note 7.

²³⁵ Jones & Cook, *supra* note 20.

she receives. However, students who are sexually active or intend to become sexually active in college would benefit from increased education.

Furthermore, adolescents and young adults who support vaccination against HPV may be eager to spread the word to their friends. In 2006, Harvard University Health Services (HUHS) began providing Gardasil© to Harvard students. Soon thereafter, 15 Harvard student organizations, including the Harvard College Women's Center, began the Harvard HPV Vaccine Awareness Campaign to lead education efforts on campus and communicate with HUHS about subsidizing the vaccine. Within a year, HUHS implemented a two-year program that reduced the price of the three-dose vaccination series from \$462 to \$75. Before HUHS offered the reduced price, 141 students received the three doses from HUHS and 403 other students received at least one of the doses from HUHS. By May 2009, HUHS reported that 1,126 students had received all three doses and another 1,237 students had received at least one dose from HUHS. Support from HUHS for subsidized vaccines has ended, due to the increased availability of the three-dose series to females before they enter college. However, education efforts by student groups continue on campus²³⁶, suggesting that Merck could have found success by appealing to peer networks.

If a mandate were the only acceptable course of action for Merck, then the targeted pre-adolescent girls should have been given the opportunity to opt-out of receiving the vaccination themselves. As discussed above, individuals within the targeted age group are competent to make decisions regarding medical conditions at this level of severity. State laws governing age

²³⁶ See Nicholas A. Ciani, *Student Groups Push HPV Education*, THE HARVARD CRIMSON, (Nov. 17, 2006), <http://www.thecrimson.com/article/2006/11/17/student-groups-push-hpv-education-two/>; Arianna Markel, *HPV Vaccine Subsidy to End July 31*, THE HARVARD CRIMSON, (July 13, 2009), <http://www.thecrimson.com/article/2009/7/13/hpv-vaccine-subsidy-to-end-july/>.

of consent to medical treatment often apply only to affirmative consent to the receipt of treatment rather than the decision to withhold consent and reject medical treatment. However, this distinction is neither psychologically appropriate nor legally necessary.

Furthermore, a mandate with a strong opt-out provision might have led to the provision of the vaccination series at an acceptable price while simultaneously achieving a reasonable balance between individual autonomy on the one hand and racial and socio-economic targeting on the other. A vaccine that has been mandated is more likely to be covered by dedicated funding at the state level and vaccination programs at the federal level than a vaccine that is optional²³⁷. Such programs include the federal Vaccines for Children Program (VFC), which provides free vaccines to children between the ages of 9 and 18 who are covered by Medicaid, uninsured, Alaskan Native, or Native American²³⁸. Just under half of children in the United States rely on VFC²³⁹. However, some commentators worry that individuals who do not qualify for assistance from these programs or live in states where funding is insufficient may be unable to afford the vaccine. A decrease in expense is particularly important because the vaccine's \$360 price tag, making Gardasil© one of the most expensive vaccines ever offered, is excessive for many of the individuals who are most in need of receiving the three-dose series²⁴⁰. Latina, African American, and Asian women are significantly more likely to contract HPV and cervical cancer than Caucasian females, particularly in poorer regions of the United States, but individuals of lower

²³⁷ Levine, *supra* note 86.

²³⁸ Kuehn, *supra* note 131, at 640.

²³⁹ National Vaccine Advisory Committee, *supra* note 132, at 147.

²⁴⁰ Globerson, *supra* note 133, at 264.

socio-economic status also are less able to pay for the vaccine and less likely to have regular Pap tests that can detect the conditions while they still can be treated²⁴¹.

The Hepatitis B vaccine provides an apt analogy. When Merck's Hepatitis B vaccine first was introduced, ACIP and the CDC recommended it only for high-risk groups, such as intravenous drug users and men who engaged in sexual activity with other men. Once the government determined that vaccine uptake was insufficient, the vaccine was mandated for all individuals and now typically is administered to infants, despite the fact that Hepatitis B – like HPV – often is transmitted through sexual contact²⁴². Targeting high-risk populations is difficult, and mandating the HPV vaccine solely for Latina, African American, and Asian females likely would be difficult to enforce and lead to strong legal challenges. Rothman and Rothman take issue with the universal, rather than racially- or socioeconomically-focused, application of the vaccine mandate and Merck's marketing strategies. In particular, they disapprove of the manner in which Merck's "One Less" advertisements mislead viewers into believing that all girls are at equal risk for contracting HPV and developing cervical cancer²⁴³.

However, Pinker stresses that statistical probabilities at the population level are not appropriate predictions of characteristics at the individual level²⁴⁴. Thus, instead of hindering the ability of individuals who do not need the vaccine to opt-out of its administration, girls should be allowed to decide whether receiving the vaccine is appropriate for them. Since state legislatures were willing to consider, and in some cases enact, legislation specific to the HPV vaccine, it likewise seems reasonable to propose that state legislatures approve an opt-out provision for

²⁴¹ ACIP MMWR, *supra* note 12, at 5-8.

²⁴² See Rothman & Rothman, *supra* note 42, at 782-83; Colgrove, *supra* note 18, at 2390.

²⁴³ Rothman & Rothman, *supra* note 42, at 782.

²⁴⁴ Lecture by Steven Pinker, Professor of Psychology, Harvard University (Spring 2007).

minors that is specific to the HPV vaccine. Such a provision would allow minors to opt-out of receiving Gardasil© regardless of their parents' views, thereby promoting individual autonomy and avoiding the danger of requiring individuals to opt-out of receiving all vaccines if they actually desire to avoid only Gardasil©.

CONCLUSION

The HPV vaccine represents a breakthrough in cancer prevention. Even groups that are adamantly opposed to making receipt of the HPV vaccine mandatory do not object to the availability of the vaccine²⁴⁵. Gardasil© has the potential to prevent the eleventh most common form of cancer in women in the United States and second most common form of cancer in women in the world, as well as the most common STI in the United States. However, the possibility of achieving these impressive results did not necessarily justify, in scientific and medical terms, the rapid mobilization of political forces in support of a vaccine mandate. Neither the public nor public health officials was included in the conversation regarding whether to impose mandates at the state level for a disease that cannot be transmitted via casual contact. Furthermore, the addition of such a controversial vaccine to the mandatory vaccination schedule may have a lasting impact on public acceptance and receipt of other vaccines as well as public trust in government.

Girls are taught from a young age the importance of being able to say “no,” and they are told that such a statement will have an effect on one’s interlocutor. The concept of consent permeates American culture in the context of sexuality and control over one’s body. Therefore, it is particularly ironic that a vaccine that protects against a disease that can be transmitted only

²⁴⁵ See Peres & Japsen, *supra* note 7; Lisa Wangsness, *Patrick Seeks \$72m Hike in Health Aid – Would Boost Prevention, Add 3 Inoculations*, THE BOSTON GLOBE, Feb. 26, 2007, at A1.

through intimate, sexual contact could be mandated. Such a move denies the power of saying no, both to the vaccine and to sexual activity, since a mandate assumes that no female actually will say no to the behavior that can cause the disease against which Gardasil© protects.

States are granted the power to determine which vaccines are mandated, a requirement only parents have the authority to avoid. However, research in the field of developmental psychology suggests that individuals over the age of 14, and possibly even as young as 9, are competent to make medical decisions, or at least participate substantially in making choices regarding their medical treatment. Legal literature analyzing age of consent laws and the competency of minors demonstrates the disconnect between the legal presumption of incompetence and the actual abilities of individuals younger than 18. These articles focus on individualized treatments for which the patients' parents must provide – or withhold – consent, rather than therapies that have been mandated. Nevertheless, their arguments still are relevant. The targeted recipients of Gardasil© should have been given a choice whether to receive the vaccine, and this choice should have been informed by more comprehensive and neutrally presented scientific and medical evidence. Advertisements that do not mention the primary mode of transmission of the conditions against which the vaccine protects do not adequately inform potential consumers of the purpose of the product. In addition, providing the public with educational materials before, rather than simultaneously or after, mandating the vaccine can increase acceptance of the vaccine. This information also can raise awareness among females outside of the targeted age group who otherwise will continue to lack knowledge of the conditions that Gardasil© prevents.

According to legal precedent governing which types of vaccines may be mandated, Gardasil© should not have been the subject of a school vaccination mandate in any state. Where

Gardasil© is available as a voluntary therapy, minors should be able to choose whether to receive this vaccine. States already have carved out exceptions to their age of consent laws for issues relating to sexual activity, such as treatment for VDs and receipt of some forms of contraception. Despite the fact that it is a vaccine, Gardasil© is more comparable to these interventions than to vaccinations that protect against polio or smallpox. Placing Gardasil© in the same category as treatment for VDs acknowledges that only volitional behavior can lead to a need for the protection conveyed by the vaccine and avoids the danger that invoking general vaccine opt-out provisions can cause.

If Merck is successful in establishing additional mandates, then the legislation related to Gardasil© should allow the targeted minors to opt-out instead of their parents. Some pre-adolescent and adolescent girls will recognize the benefits that Gardasil© can convey even if their parents do not approve of this vaccination, while other girls will know that they do not need this treatment despite their parents' assertions to the contrary. Contrary to Merck's commercials, there are at least four ways to be one less: use of condoms, abstinence, a sexual relationship with only one uninfected partner, or receipt of the vaccine²⁴⁶. These methods have varying levels of success, and the preferred strategy should be chosen by the individual who will need to live with the direct consequences.

²⁴⁶ ACIP MMWR, *supra* note 12, at 7.